

# **EXHIBIT BB**

ETHICON, INC.

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**Pelvic Floor Repair**  
**Extended Review of Medical Literature**  
**May, 2001**

R&D - CENTRAL FILE

Pelvic prolapse describes a varied and complex array of support structure failures. The response to these failures is an even more complex array of surgical interventions.

**Objective**

This document was prepared as an expansion and update of the original literature review prepared by Brigitte Hellhammer, MD in June 2000 and entitled *Meshes in Pelvic Floor Repair*. This document derives from the literature further detail regarding the surgical interventions used in the treatment of pelvic prolapse. This review examines the materials used and results reported with their use, particularly focusing on any issues associated with the material chosen. The combined literature reviews will help determine whether further evidence is needed in order to support the use of mesh materials in pelvic floor reconstruction.

**Procedure**

In June, 2000, the ETHICON, Inc. Scientific Information Service (SIS) prepared a comprehensive bibliography of the literature on the topic of materials, particularly meshes, used for gynecologic surgery. A physician trained in Obstetrics and Gynecology, who serves as a consultant to the organization, identified the articles from the bibliography that were most pertinent to this review. An additional search of subsequent literature (June 2000 – April 2001) on Pelvic Floor Repair was performed using Index Medicus. Relevant articles were added to the bibliography for this review.

**Discussion**

The review subset included 23 original and 5 review articles describing procedures that could be described as pelvic floor repair. The conditions addressed by the intervention were used as the first data classification:

- Cystocele (anterior vaginal wall)
- Rectocele (posterior vaginal wall)
- Combined defects

Surgical approach was used as the second classification:

- Vaginal
- Laparoscopic
- Abdominal
- Combined/other

Additional article identifiers included location of author (US or Europe) and mesh application (suspension, patch or both; none where mesh was not used). A table of information extracted from the original is included in Appendix A.

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## Original Articles

### Cystocele Repair

|                       |  |
|-----------------------|--|
| Approach              | Vaginal  |
| No. of articles       | 3  |
| Total Subject count   | 137  |
| Follow-up range (mos) | 21-24  |
| Materials used        | Polypropylene mesh<br>Polyester/pga mixed fiber mesh       |
| Comments              | All Grade 4 or recurrent<br>No material problems described |

Three articles were identified that focused on cystocele repair and all reported a vaginal approach.. Cystocele repair is also often a component of the combined defect repair and is described below. All patients included in these reports were diagnosed with Grade 4 cystocele or recurrent cystocele.

Among the 137 cases, no instances of mesh erosion or other material-implicated complications were described. Safir(18) frequently included other transvaginal repairs when repairing the Grade 4 cystoceles. His repair technique relies on connective tissue replacement of a temporary scaffold provided by a fully absorbable mesh and reported 92% of the patients with excellent objective and subjective results for the cystocele repair. Migliari (14) advocates the use of mesh for this intervention, expressing concerns about relying on demonstrably weakened tissue to provide the needed support.

### Rectocele Repair

|                       |   |                                    |
|-----------------------|---|------------------------------------|
| Approach              | Vaginal & Perineal  | Perineal                           |
| No. of articles       | 1   | 2                                  |
| Total Subject count   | 10  | 13                                 |
| Follow-up range (mos) | ?   | 14-29                              |
| Materials used        | PGA suture<br>PGA mesh  | Polypropylene mesh                 |
| Comments              | 3 granuloma removed<br>Improvement in coital comfort when mesh was used | No problems with material reported |

Catelo-Branco (4) reported a very small, randomized series comparing plication with absorbable mesh. He rejected the use of permanent mesh fearing rejection followed by recurrence. The use of mesh reduced the loss of vaginal mucosa that presumably explained the difference (40% vs 0%) in

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coital problems in the mesh group. Three cases required one-time removal of granulation tissue ("granulamata"), 2 in the mesh group, 1 in the plication group. Parker (17) acknowledges the potential for infection when permanent mesh is used but feels the scarring that follows mesh removal would adequately reinforce the rectovaginal septum.

#### Enterocoele Repair

|                       |              |
|-----------------------|--------------|
| Approach              | Laparoscopic |
| No. of articles       | 1            |
| Total Subject count   | 3            |
| Follow-up range (mos) | 10.5         |
| Materials used        | PGA suture   |

The only article identified describing isolated enterocoele repair described a laparoscopic technique. The limited literature is expected as enterocoele frequently occurs with other pelvic floor problems and enterocoele repair is included in the defined defects repair section.

#### Combined Defects Repair

| Approach              | Vaginal   | Laparoscopic                | Abdominal   |
|-----------------------|---|-----------------------------|---|
| No. of articles       | 7*  | 1                           | 9*  |
| Total Subject count   | 620   | 2                           | 522   |
| Follow-up range (mos) | 11 – 36   | 12                          | 3 – 32  |
| Materials used        | Suture<br>chromic<br>absorbable & non-abs<br>braided non-abs<br>monofil non abs<br>Polypropylene mesh (2)<br>PTFE mesh (sling)<br>Autologous tissue (sling) | Polypropylene mesh          | Suture<br>monofilament, abs & non<br>PTFE Mesh (3)<br>Polyester Mesh(3)<br>Polypropylene Mesh(3)    |
| Comments              | One reported mesh erosion, vaginal wall   | No reported product problem | 1 mesh infection reported<br>Mesh erosion reported, typically infrequent, high with some techniques |

\*Article 2, randomized comparison of vaginal and abdominal approach, is included twice

The largest article grouping of this series is the most varied. Although most of the procedures described include a vaginal vault suspension, the approach, site of attachment and materials used vary greatly. These procedures address the most severe cases of vaginal prolapse, simultaneously correcting several defects.

#### Vaginal Approach

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Julian (11) studied the use of polypropylene mesh applied in the area under the anterior vaginal wall segment created after anterior colporrhaphy, paravaginal repair and urethral suspension by evenly dividing a group of 24 revision patients with and without mesh. Recurrent prolapse at two-year follow-up was observed in 4/12 of the patients treated without mesh, none were observed in the mesh treatment group. Mesh problems occurred in 3/12 patients; granulation tissue causing spotting in one patient, mesh erosion in one patient and perforating mesh fibers in one case.

Meeks (13) describes a complex procedure to repair cystocele, urethrocele, rectocele, enterocele and the perineal body in a single procedure that averages 163 minutes in his series. He omits any comments about mesh but explains the choice of absorbable suture to possibly enhance local fibrosis and improve fixation. Nicita (16) uses a large piece of polypropylene to replace the reduced function of the levator ani muscle. In his series of 44 patients, he reported one incident of vaginal wall erosion, the size of a quarter, which was removed at an outpatient visit. He attributes the lack of infections possibly to the open fabric of the mesh. He further comments that reexploration, not yet attempted, and may be difficult because of fibrosis. Shull(20) acknowledged the challenge of managing the anterior compartment but continues to use only nonabsorbable braided suture for reconstruction. His concern about placing a nonabsorbable foreign body in a clean-contaminated wound leads to a refusal to consider synthetic graft materials.

#### Abdominal approach

Fox (10) described a procedure that added mesh interposition to suspension for patients with a rectocele and vault prolapse; the procedure used a single piece of Teflon mesh. She reported a single case of mesh infection (time to event not reported) which required mesh removal.

Kohili(12) described a 12% erosion rate following abdominal sacrocolpopexy. Because two of the erosion events involved exposure of suture rather than mesh, the mesh erosion rate (5/57) was 9%. The mesh erosion was in the vaginal apex in all cases and appeared, on average, 14 months after the procedure. No characteristics predictive of erosion were identified. The author reported change to cadaveric *fascia lata* as the suspensory graft material.

Visco (21) describes a combined abdominal and vaginal colpoperineopexy when posterior vaginal fascia is severely attenuated. He reported an overall erosion rate of 5.5% (including abdominal and combined approaches) but observed a far higher rate (16 to 40%) in those procedures involving combined approaches. Median time to erosion event ranged from 15.6 months for the abdominal procedures to 4.1 months for the combined procedures that included vaginal mesh placement. No predictors of mesh erosion beyond surgical approach were identified. The author suggests that mesh erosion may be a manifestation of bacterial contamination, noting consistency with the increased rate of erosion noted with the vaginal approach.

#### Review Articles

Five review articles are also included in the bibliography. The articles either focus on experiences pelvic floor reconstruction technique (R3, R4 and R4) or summarize the use of mesh in gynecologic surgery (R1 and R2).

## Summary

Mesh is used successfully in the major procedures for treatment of pelvic wall or pelvic floor prolapse. Theoretical advantages for mesh use have been described, depending on the mesh application. The two major reasons for using mesh are:

Patch to reduce the need to tighten tissues where support structures are weakened (cystocele repair)

- + reduction in recurrence  
retention of vaginal size to reduce dyspareunia
- infection intractable when mesh is present  
mesh may lose vaginal tissue covering (erosion)

A substitute for autologous or cadaveric tissue for replacement support and interposition (e.g. sacrocolpopexy)

- + no harvesting of autologous tissue  
no use of banked tissue  
material of known strength properties, especially important as autologous tissues in afflicted patients are suspect
- infection intractable when mesh is present  
mesh may lose vaginal tissue covering (erosion)

Mesh products of different fibers and construction have been used for both types of applications:

| Mesh                                      | Ref. No<br>Patch | Ref. No.<br>Support structure |
|---|------------------|-------------------------------|
| Polypropylene                             | 14,17,22         | 8,11,12,16                    |
| Polyester                                 |                  | 7,12,21                       |
| Polyglycolide                             | 4,18             |                               |
| PTFE or expanded PTFE                     |                  | 5,6,10,21                     |
| Mixed fiber (polyglycolide and polyester) | 15               | 9                             |

## Conclusion and Recommendation

There appears to be a good amount of evidence in the surgical literature documenting the use of mesh for the repair of pelvic floor defects. Pelvic floor problems are not often isolated and, as expected, the approach to their treatment is often individualized. The literature reflects a variety of applications for the use of mesh utilizing the gamut of available materials. Consistent throughout the articles reviewed

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is the lack of reported serious complications resulting from the mesh products leading us to believe that the use of mesh in pelvic floor repair is safe.

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## **Appendix A**

### **Table of Articles Reviewed**

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## Cystocele

| Approach         | Ref          | Yr   | Procedure Description   | Material used   | No. of patients | Follow (mo) | Recurrence %  | Material reaction | Comments   |
|------------------|--------------|------|---|---|-----------------|-------------|---|-------------------|--|
| Vaginal          | 14<br>E<br>I | 1997 | Anterior colporrhaphy; prox. Sutures at level of bladder neck, distal level of vaginal cuff TVT used if stress incontinence dx Enterocoele repair if needed | Polypropylene mesh fixed pga suture   | 12              | 20.5        | NR<br>75% 'cured'                                     | None              | All patients recurrent vaginal bulging preop Included TVT as part of intervention  |
|                  | 15<br>E<br>I | NR   | Four corner fixation of mesh  | Mixed fiber mesh (60% pga & 40% polyester) fixed with polypropylene suture GII titanium anchors to pubis in 5 patients  | 15              | 23.4        | 7<br>+ 2 cases of new onset enterocoele @6 mos postop | None              | Grade IV cystocele Broad spectrum IV ab 24 hrs after procedure followed by cephalosporin Foley catheter retained for 7 days                          |
|                  | 18<br>U<br>I | NR   | 4 defect repair Hysterectomy if uterine prolapse Culdoplasty Enterocoele repair   | Pga mesh for enterocoele repair and culdoplasty Polyglactin suture for suspension Crumpled pga mesh, positioned beneath bladder base Pga suture for midline cystocele | 130             | 21          | 8   | None              | Grade IV cystocele preop Although multiple repairs were performed on most patients, article focus and results discussion is on the cystocele repair. |
| Laparosco<br>pic |              |      |   |   |                 |             |   |                   |  |
| Abdominal        |              |      |   |   |                 |             |   |                   |  |

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**Rectocele**

| Approach     | Ref #  | Yr Start | Procedure Description   | Material used  | No. of patients      | Follow (mo) | Recurrence %                       | Material reaction                                  | Comments  |
|--------------|--------|----------|---|--|----------------------|-------------|------------------------------------|--|---|
| Vaginal      |        |          |   |  |                      |             |                                    |  |   |
|              | 4 E I  | 1996     | Suture: Passed interrupted suture margins of levator ani; excess posterior vaginal mucosa excised and tied down<br>Mesh: fixed over margin of rectocele with interrupted suture, no removal of vaginal tissue | Suture: polyglycolic acid<br>Mesh: polyglycolic acid fixed with pga suture | Suture: 5<br>Mesh: 5 | 12          | Suture: 0<br>Mesh: 0               | Posterior wall granulomata<br>Suture: 1<br>Mesh: 2 | Procedure included additional perineal incision<br>Randomized comparing absorbable mesh and absorbable suture |
| Laparoscopic |        |          |   |  |                      |             |                                    |  |   |
| Abdominal    | -      |          |   |  |                      |             |                                    |  |   |
| Perineal     |        |          |   |  |                      |             |                                    |  |   |
|              | 17 E I | NR       | Perineal approach   | MARLEX mesh  | 4                    | 14          | None<br>3 of 4 success, 1 improved | NR   |   |
|              | 22 E I | NR       | Perineal approach   | MARLEX mesh  | 9                    | 29          | NR                                 | NR   |   |

**Enterocoele**

| Approach     | Ref #  | Yr Start | Procedure Description         | Material used      | No. of patients | Follow (mo) | Recurrence % | Material reaction | Comments |
|--------------|--------|----------|-------------------------------|--------------------|-----------------|-------------|--------------|-------------------|----------|
| Laparoscopic |        |          |                               |                    |                 |             |              |                   |          |
|              | 3 U NM | NR       | Modified Moschowitz technique | Polyglactin suture | 3               | 10.5        | 0            | NR                |          |

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**Combined Defects**

| Approach | Ref #         | Yr Start | Procedure Description   | Material used  | No. of patients        | Follow (mo) | Recurrence %  | Material reaction | Comments   |
|----------|---------------|----------|---|--|------------------------|-------------|---|-------------------|--|
| Vaginal  |               |          |   |  |                        |             |   |                   |  |
|          | 5<br>U<br>B   | 1997     | Autologous: free vaginal wall graft<br>PTFE: patch 3.5x1.5cm<br>Sling centered under bladder neck   | Autologous tissue or PTFE (antimicrobial)<br>Both used PTFE suture | Tissue: 20<br>Mesh: 20 | 22          | NR (incontinence reported, unclear reference to cystocele recurrence) | None              | Primary interest is sling, most patients had additional pelvic floor repairs<br>Randomized comparing autologous vaginal wall sling and mesh<br>All patients had UI in addition to vaginal prolapse |
|          | 13<br>U<br>NM | 1981     | Suspension of vagina to iliococcygeus (prespinous fascia)<br>Posterior colporrhaphy<br>Perineal body repair   | Chromic suture   | 110                    | 36          |   | NR                | 75% had enterocele with associated cystocele, urethrocele, rectocele or perineal body defect<br>82% showed cystocele<br>81% had rectocele  |
|          | 16<br>E<br>I  | 1996     | Large mesh placement  | Polypropylene mesh fixed with PROLENE suture                       | 44                     | 13.9        | Partial (to first degree) 3/6 with third degree uterine prolapse      | Erosion 1 subject | 'Erosion provoked by a mesh could occur beyond one year'   |
|          | 19<br>U<br>NM | 1988     | Sutures placed with 3 points of penetration - white line, pubocervical fascia and epithelium<br>Abandoned suspension in addition to paravaginal repair as unnecessary | Nonabsorbable suture and absorbable suture                         | 62                     | 19.2        | 34  | NR                | 98% coexisting localized pelvic support defects anterior<br>100% support defects other pelvic sites<br>69% previous pelvic surgery   |
|          | 20<br>U<br>NM | NR       | Suspension<br>Side-side plication   | Nonabsorbable braided suture                                       | 302                    |             | N = 13 (evaluable) + 5 of total                                       | NR                | Refrained from synthetic graft concern about nonabsorbable foreign body in clean-contaminated wound  |

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| Approach     | Ref #        | Yr Start | Procedure Description  | Material used   | No. of patients | Follow (mo) | Recurrence %   | Material reaction | Comments  |
|--------------|--------------|----------|--|---|-----------------|-------------|--|-------------------|---|
|              | 23<br>U<br>I | NR       | Abdominal sacral<br>colpopexy<br>Abdominal enterocele<br>repair<br>Paravaginal repair<br>Culdoplasty   | MARLEX mesh<br>ETHIBOND<br>or<br>PROLENE  | 20              | 11.3        | Vault<br>prolapse 0<br>Enterocele 0<br>Cystocele<br>N= 3 | None              |   |
| Laparoscopic |              |          |  |   |                 |             |  |                   |   |
|              | 9<br>E<br>S  | NR       | Mesh attachment<br>between vaginal walls<br>and uterus and iliac<br>laparoscopic Burch<br>posterior<br>colpoperineorrhaphy   | VICRYL composite<br>mesh (2 pieces)(with<br>polyester) anchored<br>with permanent<br>polyester suture | 2               | 12          | 0  | NR                | Amoxicilline and<br>clavulanic acid IV for 2<br>days, then 10 days oral   |
| Abdominal    |              |          |  |   |                 |             |  |                   |   |
|              | 1<br>U<br>NM | NR       | Hysterectomy if uterine<br>prolapse<br>Uterosacral ligament<br>vaginal vault suspension<br>Culdoplasty to obliterate<br>cul-de-sac or posterior<br>enterocele<br>Other reconstruction as<br>required | Monofilament suture,<br>both absorbable and<br>non-absorbable   | 46              | 15.5        | 10   | NR                |   |
|              | 6<br>E<br>I  | NR       | Hysterectomy followed<br>by sacropexy<br>or<br>colpohystero-sacropexy<br>preserving uterus<br>Also some with<br>culdoplasty and anterior<br>colposuspension  | PTFE mesh   | 21              | 31.6        | 29%<br>cystocele   | NR                |   |
|              | 7<br>U<br>S  | 1995     | Abdominal sacral<br>colpopexy<br>culdoplasty   | MERSELENE mesh,<br>double thickness   | 19              | 3           | 0<br>Correction<br>was<br>complete in<br>63%             | NR                | A report of modified<br>procedure used for 19 of<br>the 97 patients who<br>underwent surgery for<br>pelvic prolapse during 1 yr |

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| Approach | Ref #  | Yr Start | Procedure Description  | Material used   | No. of patients            | Follow (mo) | Recurrence %            | Material reaction  | Comments   |
|----------|--------|----------|--|---|----------------------------|-------------|-------------------------|--|--|
|          | 8 E    | 1994     | Abdominal sacral colpopexy (ASC) Halban culdoplasty, all cases Burch colposuspension, 6 cases  | PROLENE Mesh fixed with delayed absorbable sutures on vaginal apex and permanent suture to anterior sacral fascia                             | 15                         | 20          | 0                       | None   | Irrigate with vancomycin followed by 4 days parenterally   |
|          | 10 E B | NR       | Scrocolpopexy Cystocele repair, if present   | Teflon mesh attached with polyester suture Second mesh for cystocele repair (3 cases)   | 29                         | 14          | 10                      | 1 mesh infection   |  |
|          | 11 U I | 1989     | Anterior colporrhaphy paravaginal repair urethral suspension Treatment grp included anterior vaginal segment reinforced sewed from urethrovessicle junction to vaginal apex and junction of obturator and levator fascia | MARLEX polypropylene mesh   | 12 Treatment<br>12 control | 24          | Control: 33<br>Treat: 0 | 1 erosion<br>1 granulation tissue<br>1 perforating mesh fibers   | Controlled comparison with and without mesh Procedure recommended after two or more prior operative failures   |
|          | 12 U S | NR       | Sacrocolpopexy Moschowitz culdeplasty  | Double thickness synthetic mesh MARLEX 47 cases MERSILENE 10 cases fixed with ETHIBOND secured from vaginal apex along posterior vaginal wall | 57                         | 19.9        | NR                      | Erosion 12 % (mesh and suture, 9% mesh only) occurrence mean 14.0 mos after procedure (4-24 mos) Suture erosion post prox vagain N=2, responded to cons therapy Mesh erosion at vaginal apex N = 5; required addnl surgery | Retrospective chart review 8-year period Mesh excision with vaginal advancement cured erosion with no recurrence of vault decensus No obvious predictors. Abandoned use of synthetic graft |

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| Approach | Ref<br>*     | Yr<br>Start | Procedure Description   | Material used   | No. of<br>patients                  | Follow<br>(mo) | Recurrence<br>%                | Material reaction  | Comments   |
|----------|--------------|-------------|---|---|-------------------------------------|----------------|--------------------------------|--|--|
|          | 21<br>U<br>S | 1992        | Sacral colpopexy – 155<br>sacral colperineopexies –<br>88<br>combined abd-vaginal<br>procs – 30 | MERSILENE mesh<br>in all but 4 patients<br>(received<br>GORETEX)<br>Fixed by various<br>monofilament and<br>braided permanent<br>suture | 273                                 | 12.3           | NR                             | Erosion 5.5%<br>Significantly higher<br>rates with combined<br>procedures (16 and<br>40%)<br>Time to erosion<br>appearance 15.6 mos;<br>4.1 mos with vaginal<br>mesh | Used a combined<br>abdominal/vaginal<br>approach is 16 of the 273<br>procedures<br>Theorized mesh erosion as<br>manifestation of bacterial<br>contamination – consistent<br>with finding higher erosion<br>rates with vaginal<br>placement |
| Combined | 2<br>U<br>S  | 1989        | Vaginal: bilat<br>sacrospinous vault<br>suspension<br>Abdominal: colposacral<br>suspension      | Vaginal: permanent<br>monofilament suture<br>Abdominal:<br>permanent<br>monofilament suture   | Vaginal:<br>42<br>Abdomina<br>l: 38 | 30             | Vaginal:33<br>Abdominal:<br>16 | NR   | Randomized comparison of<br>vaginal and abdominal<br>approach<br>Dyspareunia Vaginal 15%,<br>Abdominal 0%  |

\*Ref Line 2 Location: U:US; E:Europe Line3 Mesh Use: I:Interposition (Patch); S: Sling; B: Both; NM: No mesh

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## Comparison of Meshes in the Pelvic Floor Repair Studies (from Lit Review)

| Sample Description  | Material Type                             | Fabric Const. | Yarn Const.              | %Porosity      | Thickness (mils) | Unit Weight (mg/cm <sup>2</sup> ) | Burst Strength (psi) |
|---------------------|---|---------------|--------------------------|----------------|------------------|-----------------------------------|----------------------|
| Mersilene           | Polyester                                 | Knitted Mesh  | Multi-Filament 30 denier | 62.7           | 10.24            | 4.18                              | 81.75                |
| Prolene Mesh        | Polypropylene                             | Warp Knit     | Mono-Filament 5-6mil     | 52.6           | 19.41            | 7.64                              | 247.50               |
| Prolene Soft Mesh   | Polypropylene                             | Warp Knit     | Mono-Filament 3.5mil     | Not Available  | 15.84            | 4.6                               | 110.50               |
| Vypro Mesh          | 50/50 Polypropylene/<br>90/10 PGA/<br>PLA | Warp Knit     | Multi-Filament for both  | 70.8           | 17.31            | 5.75                              | 90.24                |
| PTFE or e-PTFE      | Polytetrafluoro-ethyl                     | Extruded Film | Not Applicable           | Not Applicable | Not Available    | Not Avail.                        | Not Avail.           |
| Mixed Fiber PGA/PET | PGA/<br>PET                               | Mesh          | Multi-Filament           | Not Available  | Not Available    | Not Avail.                        | Not Avail.           |

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